

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Kyogo ITOH et al.

Serial No. 10/586,499

Filed July 20, 2006

:

:

:

:

Mail Stop: PCT

Attorney Docket No. 2006_1150A

EPIDERMAL GROWTH FACTOR
RECEPTOR-DERIVED PEPTIDES
[Corresponding to PCT/JP2005/000786
Filed January 21, 2005]

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application
PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No.
_____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the
above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

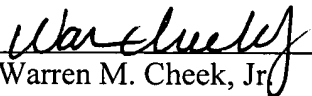
a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Kyogo ITOH et al.

By 
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
October 23, 2006

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: October 23, 2006

ATTY DOCKET NO.
2006_1150ASERIAL NO.
10/586,499APPLICANT
Kyogo ITOH et al.FILING DATE
July 20, 2006

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AB						
	AC						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AD	T. Yamamoto et al., "Similarity of protein encoded by the human <i>c-erb-B-2</i> gene to epidermal growth factor receptor", <i>Nature</i> , Vol. 319, pp. 230-234, January 16, 1986.					
	AE	L. Coussens et al., "Tyrosine kinase receptor with extensive homology to EGF receptor shares chromosomal location with <i>neu</i> oncogene", <i>Science</i> , Vol. 230, pp. 1132-1139, December 1985.					
	AF	D. S. Salomon et al., "Epidermal growth factor-related peptides and their receptors in human malignancies", <i>Critical Reviews in Oncology/Hematology</i> , Vol. 19, pp. 183-232, 1995.					
	AG	V. A. Miller et al., "Pilot trial of the epidermal growth factor receptor tyrosine kinase inhibitor gefitinib plus carboplatin and paclitaxel in patients with stage IIIB or IV non-small-cell lung cancer", <i>Journal of Clinical Oncology</i> , Vol. 21, No. 11, pp. 2094-2100, June 1, 2003.					
	AH	M. Fukuoka et al., "Multi-institutional randomized phase II trial of gefitinib for previously treated patients with advanced non-small-cell lung cancer", <i>Journal of Clinical Oncology</i> , Vol. 21, No. 12, pp. 2237-2246, June 15, 2003.					
	AI	G. E. Peoples et al., "Breast and ovarian cancer-specific cytotoxic T lymphocytes recognize the same HER2/ <i>neu</i> -derived peptide", <i>Proc. Natl. Acad. Sci.</i> , Vol. 92, pp. 432-436, January 1995.					
	AJ	B. Fisk et al., "Identification of an immunodominant peptide of HER-2/ <i>neu</i> protooncogene recognized by ovarian tumor-specific cytotoxic T lymphocyte lines", <i>J. Exp. Med.</i> , Vol. 181, pp. 2109-2117, June 1995.					
	AK	I. Kawashima et al., "Identification of HLA-A3-restricted cytotoxic T lymphocyte epitopes from carcinoembryonic antigen and HER-2/ <i>neu</i> by primary <i>in vitro</i> immunization with peptide-pulsed dendritic cells", <i>Cancer Research</i> , Vol. 59, pp. 431-435, January 15, 1999.					
	AL	T. Okugawa et al., "A novel human HER2-derived peptide homologous to the mouse K ^d -restricted tumor rejection antigen can induce HLA-A24-restricted cytotoxic T lymphocytes in ovarian cancer patients and healthy individuals", <i>Eur. J. Immunol.</i> , Vol. 30, pp. 3338-3346, 2000.					

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 3		INFORMATION DISCLOSURE STATEMENT					
FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary) Date Submitted to PTO: October 23, 2006		ATTY DOCKET NO. 2006_1150A		SERIAL NO. 10/586,499			
		APPLICANT Kyogo ITOH et al.				FILING DATE July 20, 2006	
		GROUP					
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	BB						
	BC						
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BD	M. Noguchi et al., "Induction of cellular and humoral immune responses to tumor cells and peptides in HLA-A24 positive hormone-refractory prostate cancer patients by peptide vaccination", The Prostate, Vol. 57, pp. 80-92, 2003.					
	BE	Y. Sato et al., "Immunological evaluation of peptide vaccination for patients with gastric cancer based on pre-existing cellular response to peptide", Cancer Science, Vol. 94, No. 9, pp. 802-808, September 2003.					
	BF	T. Mine et al., "Immunological evaluation of CTL precursor-oriented vaccines for advanced lung cancer patients", Cancer Sci., Vol. 94, No. 6, pp. 548-556, June 2003.					
	BG	M. H. Parkar et al., "Expression of growth-factor receptors in normal and regenerating human periodontal cells", Archives of Oral Biology, Vol. 46, pp. 275-284, 2001.					
	BH	M. L. Disis et al., "High-titer HER-2/neu protein-specific antibody can be detected in patients with early-stage breast cancer", Journal of Clinical Oncology, Vol. 15, No. 11, pp. 3363-3367, November 1997.					
	BI	E. Jager et al., "Induction of primary NY-ESO-1 immunity: CD8 + T lymphocyte and antibody responses in peptide-vaccinated patients with NY-ESO-1 + cancers", Proc. Natl. Acad. Sci., Vol. 97, No. 22, pp. 12198-12203, October 24, 2000.					
	BJ	S. Ohkouchi et al., "Non-mutated tumor-rejection antigen peptides elicit type-I allergy in the majority of healthy individuals", Tissue Antigens, Vol. 59, pp. 259-272, 2002.					
	BK	N. Kawamoto et al., "IgG reactive to CTL-directed epitopes of self-antigens is either lacking or unbalanced in atopic dermatitis patients", Tissue Antigens, Vol. 61, pp. 352-361, 2003.					
	BL	T. Imanishi et al., "Allele and haplotype frequencies for HLA and complement loci in various ethnic groups", In: Proceedings of the Eleventh International Histocompatibility Workshop and Conference, pp. 1065-1220, Oxford University Press, Oxford, United Kingdom, 1992.					
EXAMINER				DATE CONSIDERED			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: October 23, 2006

ATTY DOCKET NO.
2006_1150ASERIAL NO.
10/586,499APPLICANT
Kyogo ITOH et al.FILING DATE
July 20, 2006

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	CB						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	CC	J. Dancey et al., "Issues and Progress with Protein Kinase Inhibitors for Cancer Treatment", Nature Rev. Drug Discovery, Vol. 2, pp. 296-313, April 2003.
	CD	Y. Yarden et al., "Untangling the ErbB signalling network", Nature Rev. Molecular Cell Biology, Vol. 2, pp. 127-137, February 2001.
	CE	J. Baselga et al., "Why the epidermal growth factor receptor? The rationale for cancer therapy", The Oncologist, Vol. 7, Suppl. 4, pp. 2-8, 2002.
	CF	R. S. Herbst et al., "Selective oral epidermal growth factor receptor tyrosine kinase inhibitor ZD1839 is generally well-tolerated and has activity in non-small-cell lung cancer and other solid tumors: Results of a Phase I trial", Journal of Clinical Oncology, Vol. 20, No. 18, pp. 3815-3825, September 15, 2002.
	CG	Ch. Dittich et al., "Phase I and pharmacokinetic study of BIBX 1382 BS, an epidermal growth factor receptor (EGFR) inhibitor, given in a continuous daily oral administration", European Journal of Cancer, Vol. 38, pp. 1072-1080, 2002.
	CH	J. Mendelsohn et al., "Status of epidermal growth factor receptor antagonist in the biology and treatment of cancer", Journal of Clinical Oncology, Vol. 21, No. 14, pp. 2787-2799, July 15, 2003.
	CI	C. Meyer zum Buschenfelde et al., "The generation of both T killer and Th cell clones specific for the tumor-associated antigen HER2 using retrovirally transduced dendritic cells", The Journal of Immunology, Vol. 167, pp. 1712-1719, 2001.
	CJ	D. K. Moscatello et al., "A naturally occurring mutant human epidermal growth factor receptor as a target for peptide vaccine immunotherapy of tumors", Cancer Research, Vol. 57, pp. 1419-1424, April 15, 1997.
	CK	A. Ullrich et al., "Human epidermal growth factor receptor cDNA sequence and aberrant expression of the amplified gene in A431 epidermoid carcinoma cells", Nature, Vol. 309, pp. 418-425, May 31, 1984.
	CL	A. T. Baron et al., "Monoclonal antibodies specific for peptide epitopes of the epidermal growth factor receptor's extracellular domain", Hybridoma, Vol. 16, No. 3, pp. 259-271, 1997.
	CM	H. Shomura et al., "Identification of epidermal growth factor receptor-derived peptides recognised by both cellular and humoral immune responses in HLA-A24* non-small cell lung cancer patients", European Journal of Cancer, Vol. 40, pp. 1776-1786, 2004.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.